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United States District Court
Northern District of Indiana

Ryan Klaassen, Jaime Carini, D.J.B., by and though his next friend and father, Daniel G. Baumgartner**, Ashlee Morris, Seth Crowder, Macey Policka, Margaret Roth,** and **Natalie Sperazza**, *Plaintiffs*, *v.* **The Trustees of Indiana University**, *Defendant*.	**Civ. No. 1:21-cv-238-DRL-SLC**

DECLARATION OF PETER A. MCCULLOUGH, MD, MPH

Pursuant to 28 U.S.C. §1746, I, Peter A. McCullough, MD, MPH, declare under the penalty of perjury of the laws of the United States of America, and state upon personal knowledge that:

Background and Qualifications

1. I am an adult of sound mind, 58 years old, and make this statement voluntarily, based upon my own personal knowledge, education, facts or data, and experience, and under the penalty of perjury of the laws of the United States of America.

2. I am competent to testify as a medical expert to the facts and matters set forth herein. The facts and matters set forth herein are the type of facts and matters that medical experts rely upon to reach expert conclusions. A true and accurate copy of my *curriculum vitae* is attached hereto as Exhibit A.

3. After receiving a bachelor's degree from Baylor University, I completed my medical degree as an Alpha Omega Alpha graduate from the University of Texas Southwestern Medical

School in Dallas. I went on to complete my internal medicine residency at the University of Washington in Seattle, a cardiology fellowship including service as Chief Fellow at William Beaumont Hospital, and a master's degree in public health in the field of epidemiology at the University of Michigan.

4. I am board certified in internal medicine and cardiovascular disease and hold an additional certification in clinical lipidology, and previously echocardiography. I participate in the maintenance of certification programs by the American Board of Internal Medicine for both Internal Medicine and Cardiovascular Diseases. I am on the medical staff at Baylor University Medical Center and Baylor Jack and Jane Hamilton Heart and Vascular Hospital, in Dallas, Texas. I am also on staff at Baylor Heart and Vascular Institute, which promotes cardiovascular research and education. I practice internal medicine and clinical cardiology as well as teach, conduct research, and I am an active scholar in medicine with roles as an author, editor-in-chief of two peer-reviewed journals, editorialist, and reviewer at dozens of major medical journals and textbooks. I am Professor of Medicine at Texas A & M University School of Medicine, Baylor Dallas Campus.

5. I have led clinical, education, research, and program operations at major academic centers (Henry Ford Hospital, Oakland University William Beaumont School of Medicine) as well as academically oriented community health systems. I spearheaded the clinical development of in vitro natriuretic peptide and neutrophil gelatinase associated lipocalin assays in diagnosis, prognosis, and management of heart and kidney disease now used worldwide. I also led the first clinical study demonstrating the relationship between severity of acute kidney injury and mortality after myocardial infarction. I have contributed to the understanding of the epidemiology

of chronic heart and kidney disease through many manuscripts from the Kidney Early Evaluation Program Annual Data Report published in the American Journal of Kidney Disease and participated in clinical trial design and execution in cardiorenal applications of acute kidney injury, hypertension, acute coronary syndromes, heart failure, and chronic cardiorenal syndromes. I participated in event adjudication (involved attribution of cause of death) in trials of acute coronary syndromes, chronic kidney disease, heart failure, and data safety and monitoring of anti-diabetic agents, renal therapeutics, hematology products, and gastrointestinal treatments. I have served as the chairman or as a member of over 20 randomized trials of drugs, devices, and clinical strategies. Sponsors have included pharmaceutical manufacturers, biotechnology companies, and the National Institutes of Health.

6. I frequently lecture and advise on internal medicine, nephrology, and cardiology to leading institutions worldwide. I am recognized by my peers for my work on the role of chronic kidney disease as a cardiovascular risk state. I have over 1,000 related scientific publications, including the "Interface between Renal Disease and Cardiovascular Illness" in Braunwald's Heart Disease Textbook. My works have appeared in the *New England Journal of Medicine*, *Journal of the American Medical Association*, and other top-tier journals worldwide. I am a senior associate editor of the *American Journal of Cardiology*.. I have testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs, the U.S. Food and Drug Administration Cardiorenal Advisory Panel and its U.S. Congressional Oversight Committee, The New Hampshire Senate, the Colorado House of Commons, and the Texas Senate Committee on Health and Human Services.

7. I am a Fellow of the American College of Cardiology, the American Heart Association,

the American College of Physicians, the American College of Chest Physicians, the National Lipid Association, the Cardiorenal Society of America, and the National Kidney Foundation. I am also a Diplomate of the American Board of Clinical Lipidology.

8. In 2013, I was honored with the International Vicenza Award for Critical Care Nephrology for my contribution and dedication to the emerging problem of cardiorenal syndromes. I am a founding member Cardiorenal Society of America, an organization dedicated to bringing together cardiologists and nephrologists and engage in research, improved quality of care, and community outreach to patients with both heart and kidney disease.[1]

9. I am the current President of the Cardiorenal Society of America, a expert organization dedicated to advancing research and clinical care for patients who have combined heart and kidney disease. I am the Editor-in-Chief of *Cardiorenal Medicine*, a primary research journal listed by the National Library of Medicine which is the only publication with a primary focus on research concerning patients with combined heart and kidney disease. Finally, I am the Editor-in-Chief of *Reviews in Cardiovascular Medicine*, a widely read journal that publishes reviews on contemporary topics in cardiology and is also listed by the National Library of Medicine.

10. My appended *curriculum vitae* further demonstrates my academic and scientific achievements and provides a list of publications authored by me in the past 30 years.

11. Since the outset of the pandemic, I have been a leader in the medical response to the COVID-19 disaster and have published "Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection," the first synthesis of sequenced

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[1] *See* http://www.cardiorenalsociety.org/.

multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the *American Journal of Medicine* and updated in *Reviews in Cardiovascular Medicine*.[2] I have 40 peer-reviewed publications on the COVID-19 infection cited in the National Library of Medicine. Through a window to public policymakers, I have contributed extensively on issues surrounding the COVID-19 crisis in a series of OPED's for *The Hill.* I testified on the SARS-CoV-2 outbreak in the U.S. Senate Committee on Homeland Security and Governmental Affairs on November 19, 2020. I testified on lessons learned from the pandemic response in the Texas Senate Committee on Health and Human Services on March 10, 2021, and on early treatment of COVID-19 the Colorado General Assembly on March 31, 2021. Additionally, I testified in the New Hampshire Senate on legislation concerning the investigational COVID-19 vaccine on April 14, 2020. My expertise on the SARS-CoV-2 infection and COVID-19 syndrome, like that of infectious disease specialists, is approximately 18 months old with review of hundreds of manuscript and with the care of many patients with acute COVID-19, post-COVID-19 long-hauler syndromes, and COVID-19 vaccine injury syndromes including neurologic damage, myocarditis, and a variety of

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[2] McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805 available at https://pubmed.ncbi.nlm.nih.gov/32771461/; McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997 available at https://pubmed.ncbi.nlm.nih.gov/33387997/; *see also* https://ijirms.in/index.php/ijirms/article/view/1100

other internal medicine problems that have occurred after the mRNA and adenoviral DNA COVID-19 vaccines. I have formed my opinions in close communications with many clinicians around the world based on in part our collective clinical experience with acute and convalescent COVID-19 cases as well has closely following the preprint and published literature on the outbreak. I have specifically reviewed key published rare cases and reports concerning possible recurrence of SARS-CoV-2 in patients who have survived an initial episode of COVID-19 illness.

12. My compensation rates are as follows: I am working on this case Pro Bono.

Methodologies and Analysis of COVID Generally

13. The CDC recently reported the lowest number of cases since March of 2020 (the beginning of the COVID pandemic). Sam Baker & Andrew Witherspoon, *COVID-19 cases hit lowest point in U.S. since pandemic began*, AXIOS (June 3, 2021), https://www.axios.com/coronavirus-cases-infections-vaccines-success-fa7673a1-0582-4e69-aefb-3b5170268048.html.

14. Further, according to my research, herd immunity is calculated by a specific formula, as follows: ((CC*6) + V + (.15*P)) ÷ P = HIN.

CC= COVID cases in the state

6= the current CDC multiplier[3]

V= number of vaccinated in the state

15% = the number of people in a given state that will not get COVID

[3] Centers for Disease Control and Prevention, Estimated Disease Burden of COVID-19 (May 19, 2021), https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

P=Population of a state (i.e. Indiana)

HIN=Herd Immunity Totals

15. The values subject to variables per state for the formula noted in paragraph 14 for the State of Indiana are as follows:

CC = 753,000[4]

V = 2,880,635[5]

P = 6,732,000

Thus, the HIN for Indiana is 8,408,435, calculated as follows:

(753,000 * 6) + 2,880,635 + (.15 * 6,732,000) = 8,408,435

16. The HIN for Indiana equals 125% of the state. The HIN is in excess of 100% due to the overlap of people who were infected with COVID and also received the vaccine, and thus are counted twice. This means that the multiplier for suspected COVID19 could be much more conservative and lower than what is in the current equation. While neither the CDC nor the State of Indiana have reported the number of people who have had both COVID and a vaccine for COVID, the percentage of overlap would have to be over 50% to get below the number for herd immunity to fall below 70%, which is very unlikely.

17. Because of inferred herd immunity, infection rates continue to decline. According to the official Indiana COVID numbers, the infection rate was a mere 3.1% on June 24, 2021, and it continues to decline daily, as shown in Table 1 below.

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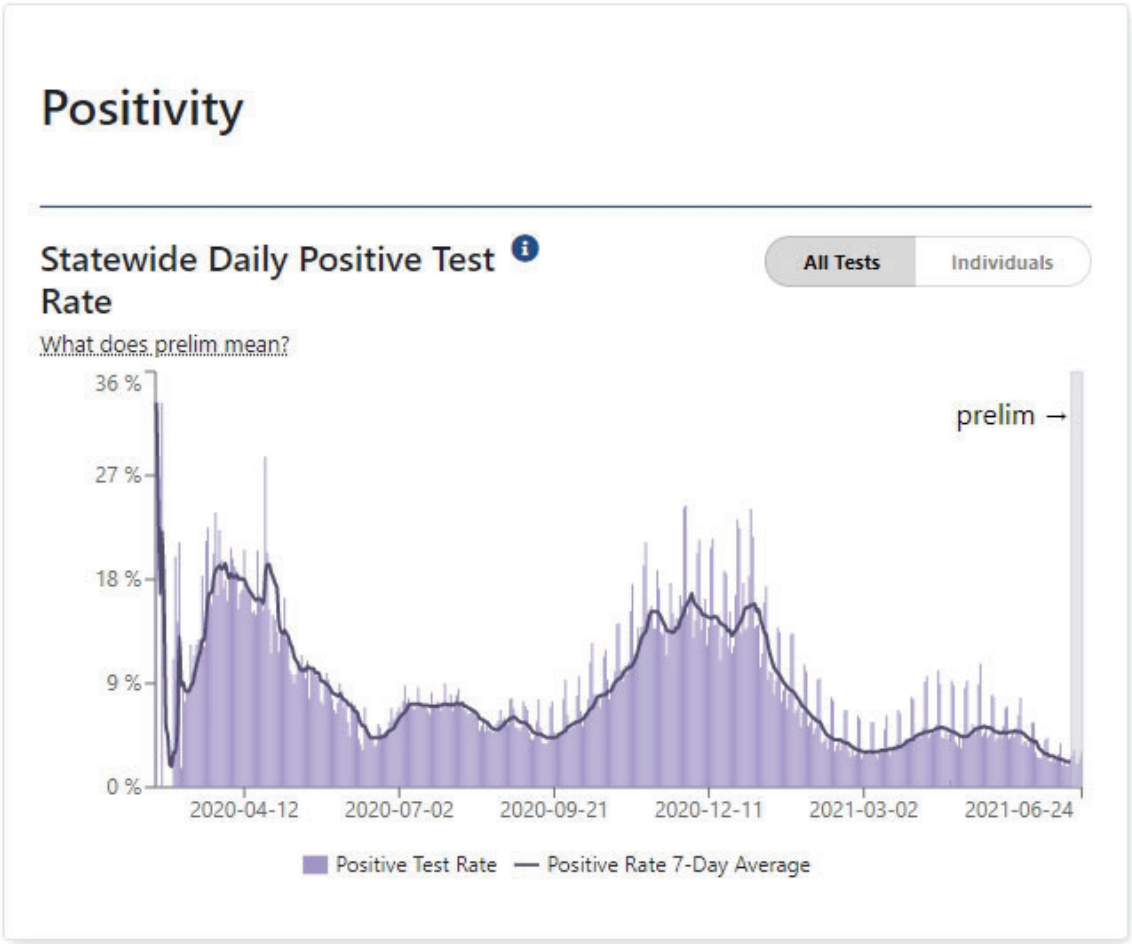
[4] Indiana State Department of Health, *Indiana COVID-19 Dashboard and Map* (June 18, 2021), https://www.coronavirus.in.gov/2393.htm (last visited June 20, 2021).

[5] Indiana State Department of Health, *Vaccine Dashboard*, (June 18, 2021), https://www.coronavirus.in.gov/vaccine/2680.htm (last visited June 20, 2021).

Table 1: **COVID Positivity Rates in Indiana**



Indiana State Department of Health, *Indiana COVID-19 Dashboard and Map* (June 27, 2021), https://www.coronavirus.in.gov/2393.htm.

18. The June 19, 2021, infection rate was only 2.7%. *Id*.

19. The positivity test rate for new COVID cases at IU-Bloomington was 0%. Indiana University, *IU Bloomington COVID-19 Testing Dashboard*, https://www.iu.edu/covid/dashboard/bloomington (last visited June 27, 2021). The highest IU infection rate ever was 7.51% on August 30, 2020, and it has steadily declined since then with no

indication of a new wave. *Id*.

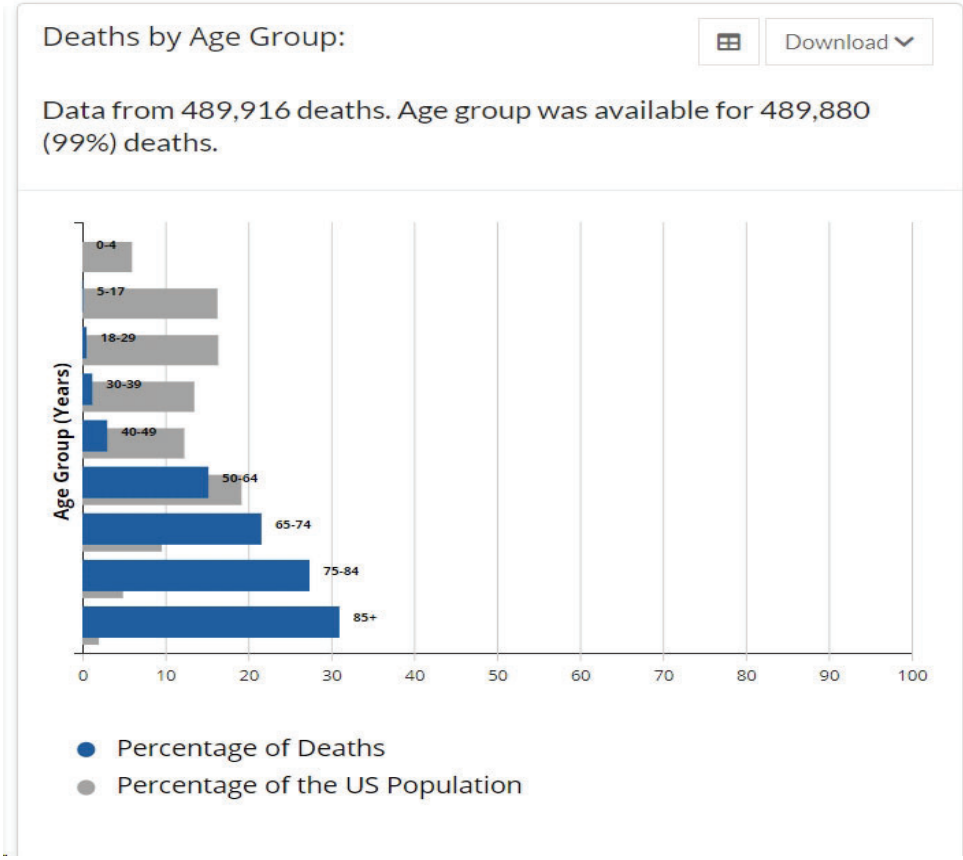
20. In my expert medical opinion, as the COVID case numbers continue to decline, requiring all IU students to be vaccinated is not reasonable from a policy perspective and is not medically necessary nor safe from a clinical perspective.

College-Age Individuals and COVID

21. In addition, in my expert medical opinion and as the table below shows, there is little to no risk for serious injury or hospitalization for COVID-19 among college age students.

Table 2: COVID Deaths by Age Group in the U.S. as of June 27, 2021:

Source: https://covid.cdc.gov/covid-data-tracker/#demographics



22. Further, the CDC has released charts depicting the risks by age, as shown below.

Table 3: COVID Rate Ratios by Age

Source: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html (Last Checked, June 27, 2021).

Risk for COVID-19 Infection, Hospitalization, and Death By Age Group

Updated June 24, 2021 Print

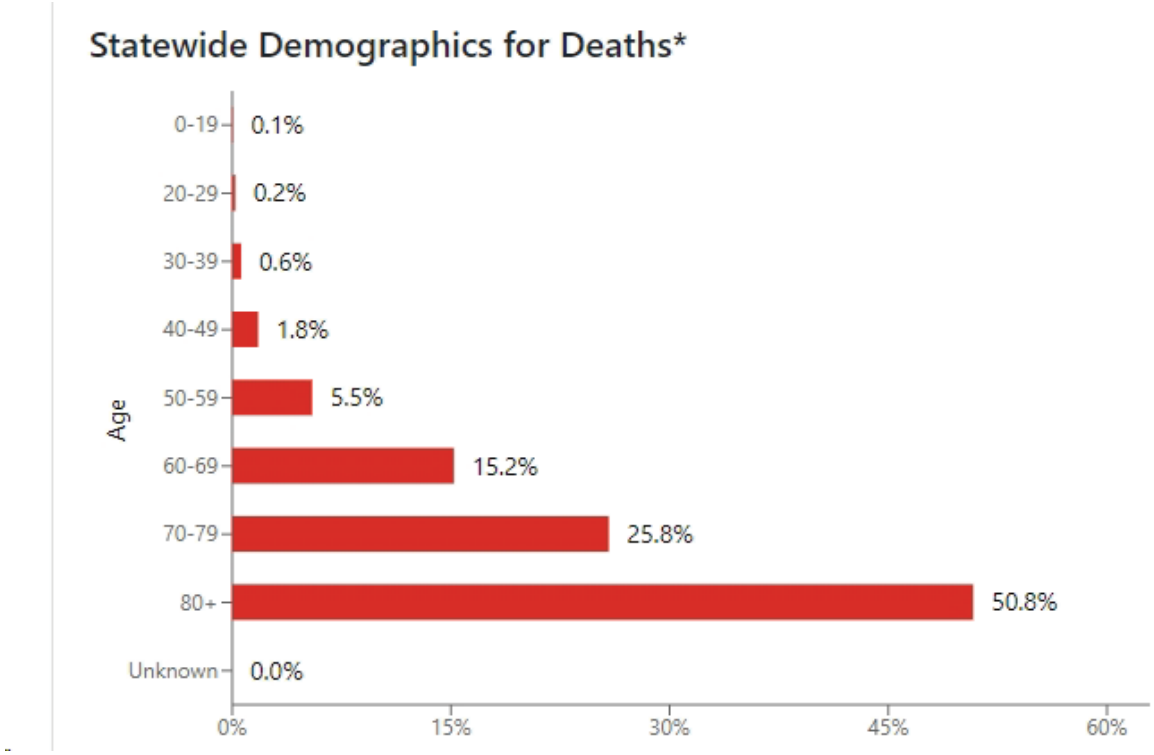
Rate ratios compared to 18- to 29-year-olds[1]

	0-4 years old	5-17 years old	18-29 years old	30-39 years old	40-49 years old	50-64 years old	65-74 years old	75-84 years old	85+ years old
Cases[2]	<1x	1x	Reference group	1x	1x	1x	1x	1x	1x
Hospitalization[3]	<1x	<1x	Reference group	2x	2x	4x	6x	9x	15x
Death[4]	<1x	<1x	Reference group	4x	10x	35x	95x	230x	610x

All rates are relative to the 18- to 29-year-old age category. This group was selected as the reference group because it has accounted for the largest cumulative number of COVID-19 cases compared to other age groups. Sample interpretation: Compared with 18- to 29-year-olds, the rate of death is four times higher in 30- to 39-year-olds, and 610 times higher in those who are 85 years and older. (In the table, a rate of 1x indicates no difference compared to the 18- to 29-year-old age category.)

Table 4: Indiana Demographic Data for COVID Deaths

Source: https://www.coronavirus.in.gov/2393.htm (Last Checked June 27, 2021).



23. Indiana COVID deaths total 13,399 from March 16, 2020 through June 23, 2021. *Id.* Indiana tracks the numbers of residents by age groups. *See* Indiana Data Hub, accessed at https://hub.mph.in.gov/dataset/population-by-age-groups/resource/0aaeb2dc-3702-4a02-aec6-d9ea8a4fce73. Thus, the COVID death rate per age group in Indiana can be calculated as follows:

$$\frac{(13{,}399) * (\text{COVID Death Percentage of age group from Table 4})}{\text{Number of Indiana Residents in the Same Age Group}}$$

Using this calculation, the following chart comprises the COVID death rate per age group in Indiana, as of June 23, 2021:

Age Group	**COVID Death Rate per Age Group**
0-19	.0008%
20-29	.002%
30-39	.010%
40-49	.029%
50-59	.081%
60-69	.289%
70-79	.898%
80+	2.80%

24. These tables and charts show the minimal risk 18-29 year olds face across the United States and in Indiana. For example, for every one 18-29 year old that dies from COVID, four 30-39 year olds die, ten 40-49 year olds die, thirty-five 50-64 year olds die, ninety-five 65-74 year olds die, 230 75-84 year olds die, and 610 over 85 years of age die. *See* Table 3.

25. Despite a high frequency of COVID infections, as determined by standard testing, serious COVID cases among college and graduate students is a rare event. Brown University physician

epidemiologist, Andrew Bostom, MD, MS, compiled data from 100 major university and college COVID data dashboards, in conjunction with national and local news reports of campus-related hospitalizations, August 2020 through the November 2020, Thanksgiving holiday break (11/22/20). *See* Exhibit 7 to Compl., ECF No. 1-8.

26. In my expert medical opinion, epidemic spread of COVID, like all other respiratory viruses, notably influenza,[6] is driven by symptomatic persons; asymptomatic spread is trivial and inconsequential.

27. A meta-analysis of contact tracing studies published in The Journal of the American Medical Association showed asymptomatic COVID spread was 0.7%. Zachary J. Madewell, PhD; Yang Yang, PhD; Ira M. Longini Jr, PhD; M. Elizabeth Halloran, MD, DSc; Natalie E. Dean, PhD, *Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis*, JAMA Network Open, available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102 (last visited June 20, 2021).

28. Accordingly, a rational and ethical prevention measure to reduce the spread of COVID is a simple requirement, as part of formal policies, that persons with active symptomatic, febrile (feverish) respiratory illnesses, like COVID, should isolate themselves. Indeed during the H1N1 influenza A pandemic, fully open, unmasked college campuses were advised by federal health officials*, "Flu-stricken college students should stay out of circulation"* and *"if they can't avoid contact they need to wear surgical masks."* Great Falls Tribune, *Advice: Flu-stricken college*

[6] Eleni Patrozou & Leonard A. Mermel, *Does Influenza Transmission Occur from Asymptomatic Infection or Prior to Symptom Onset?*, 124 Pub. Health Rep. 193 (2009).

students should stay out of circulation, August 21, 2009, page 5, section A, available at https://www.newspapers.com/image/243611045.

29. Further, college students are not the spreaders of the virus to the community. A recent study from Dr. Arnold and colleagues that reported the results of a longitudinal serosurvey (blood sampling) of community residents in Centre County, Pennsylvania, home to Pennsylvania State University, University Park campus. *See* Callum R K Arnold, Sreenidhi Srinivasan, Catherine M Herzog, Abhinay Gontu, Nita Bharti, Meg Small, Connie J Rogers, Margeaux M Schade, Suresh V Kuchipudi, Vivek Kapur, Andrew Read, Matthew J Ferrari, *SARS-CoV-2 Seroprevalence in a University Community: A Longitudinal Study of the Impact of Student Return to Campus on Infection Risk Among Community Members*, medRXiv (Feb. 19, 2021), available at https://pubmed.ncbi.nlm.nih.gov/33619497/ (last visited June 20, 2021).

30. The return of approximately 35,000 students to the campus in August 2020 increased the county population size by nearly 20%. *Id*. Over 4,500 cases of COVID infections were detected among the student population during the Fall 2020 term (before and just after student return). *Id*. Between August 7, 2020, and October 2, 2020, these investigators enrolled community residents and tested their serum for the presence of anti-Spike Receptor Binding Domain (S/RBD) IgG (a class of immunoglobulin "antibodies"), to confirm prior COVID exposure. *Id*. This was repeated in the same community during December 2020 (after the departure of students), and seroprevalence for both sampling waves was recorded and analyzed. Moreover, returning students were enrolled in a longitudinal cohort, and IgG seroprevalence results were reported from the first wave of sampling (between October and November 2020, prior to the end of the term). Here is how Arnold and colleagues summarized their findings:

> Of 345 community participants, 19 (5.5%) were positive for SARS-CoV-2 IgG antibodies at their first visit between 7 August and 2 October. Of 625 returning student participants, 195 (31.2%) were positive for SARS-CoV-2 antibodies between 26 October and 23 November. 28 (8.1%) of the community participants had returned a positive result by 9 December. Only contact with known SARS-CoV-2-positive individuals and attendance at small gatherings (20-50 individuals) were significant predictors of IgG antibodies among returning students (adjusted odds ratio, 95% Confidence Interval: 3.24, 2.14-4.91, $p<0.001$; and 1.62, 1.08-2.44, $p<0.05$; respectively).

They concluded:

> Despite high seroprevalence observed within the student population, seroprevalence in a longitudinal cohort of community residents was low and stable from before student arrival for the Fall 2020 term to after student departure, implying limited transmission between these cohorts...The demographic shift associated with student return to campus was not associated with increased SARS-CoV-2 seroprevalence in this cohort of community residents.

Id.

31. College students face little chance of actually catching COVID and little chance of spreading it to the greater community.

Advances in COVID Treatments

32. Even if students contract the virus, the treatment of the infection has improved tremendously since the advent of COVID. Studies have shown several different treatment methods, which have proven effective. A combination of medications, supported by the Association of American Physicians and Surgeons, for a minimum of five days and acutely administered supplements used for the initial ambulatory patient with suspected and or confirmed COVID-19 (moderate or greater probability) has proven effective. Brian C Procter, Casey Ross, Vanessa Pickard, Erica Smith, Cortney Hanson, Peter A McCullough, *Clinical outcomes after*

early ambulatory multidrug therapy for high-risk SARS-CoV-2 (COVID-19) infection, Reviews in Cardiovascular Medicine (December 30, 2020), available at https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.260 (last visited June 26, 2021), summarized in Table 5 below; *see also*, https://ijirms.in/index.php/ijirms/article/view/1100

Table 5: COVID Treatments

Agent (drug)	Rationale
Zinc	Inhibits SARS-CoV-2 RNA synthesis
Hydroxychloroquine 200 mg po bid	Inhibits endosomal transfer of virions, anti-inflammatory
Ivermectin (200 mcg/kg) usual dose 12 mg po qd x 3 days	Attenuates importin α/β-mediated nuclear transport of SARS-CoV-2 into nucleus
Azithromycin 250 mg po bid	Covers respiratory bacterial pathogens in secondary infection
Doxycycline 100 mg po bid	Covers respiratory bacterial pathogens in secondary infection
Inhaled budesonide, Dexamethasone 8 mg IM	Treats cytokine storm
Folate, thiamine, vitamin B-12	Reduce tissue oxidative stress
Intravenous fluid	Intravascular volume expansion

33. I, along with my colleagues, conducted the study referenced in paragraph 32, which evaluated patients between the ages of 12 and 89 years. The average age was 50.5 and 61.6% were women. The study found that primary care physicians can treat COVID patients with low hospitalization and death. The study showed that administration of the medicines and supplements shown in Table 5 produces a less than 2% chance of facing hospitalization or death among high risk adults (age over 50 with medical problems). As this study was done with mainly higher risk patients at the peak of the pandemic, this is a highly successful treatment plan and just one of the many new treatments that have been used in the last year. *Id*.; *see also* National Institutes of Health, *Therapeutic Management of Adults With COVID-19* (Updated May 24, 2021),

https://www.covid19treatmentguidelines.nih.gov/management/therapeutic-management/ (last visited June 21, 2021).

34. Treatment has improved so drastically for COVID that according to the CDC, there were 16 deaths in Indiana for young adults aged 18-29 in 2020, but zero in 2021. This is evidence of better treatment and less risk for college aged students and a generally lowered virulence for the SARS-CoV-2 strains as the pandemic progresses over time.

35. In my expert medical opinion, the combination of lowering COVID rates, the likelihood of herd immunity in Indiana, the low risk of hospitalization and death among college-aged students, and the drastically improved treatment options make IU's Mandate that all IU students (not exempted) participate in the investigational COVID-19 vaccine sponsored by the US FDA and CDC, unreasonable from a scientific and medical perspective.

COVID Vaccine Research and Development

36. The COVID-19 genetic vaccines (Pfizer, Moderna, J&J) skipped testing for genotoxity, mutagenicity, teratogencity, and oncogenicity. In other words, it is unknown whether or not these products will change human genetic material, cause birth defects, reduce fertitility, or cause cancer.

37. The Pfizer, Moderna, and JNJ vaccines are considered "genetic vaccines" or vaccines produced from gene therapy molecular platforms.[7],[8] They have a dangerous mechanism of action

[7] To KKW, Cho WCS. An overview of rational design of mRNA-based therapeutics and vaccines. Expert Opin Drug Discov. 2021 May 31. doi: 10.1080/17460441.2021.1935859. Epub ahead of print. PMID: 34058918.

[8] Doerfler W. Adenoviral Vector DNA- and SARS-CoV-2 mRNA-Based Covid-19 Vaccines: Possible Integration into the Human Genome - Are Adenoviral Genes Expressed in Vector-based Vaccines? Virus Res. 2021 Jun 1;302:198466. doi: 10.1016/j.virusres.2021.198466. Epub ahead of print. PMID: 34087261; PMCID: PMC8168329.

in that they all cause the body to make an uncontrolled quantity of the pathogenic spike protein from the SARS-CoV-2 virus. This is unlike all other vaccines where there is a set amount of antigen or live-attenuated virus. This means for the Pfizer, Moderna, and J&J vaccines it is not predictable among patients who will produce more or less of the spike protein. The spike protein itself has been demonstrated to injure vital organs such as the brain, heart, lungs, as well as damage blood vessels and directly cause blood clots. Additionally, because these vaccines infect cells within these organs, the generation of spike protein within heart and brain cells in particular, causes the body's own immune system to attack these organs. This is abundantly apparent with the burgeoning number of cases of myocarditis or heart inflammation among individuals below age 30 years.[9] The Centers for Disease Control has held emergency meetings on this issue and the medical community is responding to the crisis and the US FDA has issued a warning on the Pfizer and Moderna vaccines for myocarditis.[10] It is known that myocarditis causes injury to heart muscle cells and may result in permanent heart damage leading to heart failure, arrhythmias, and cardiac death. Because this risk is not predictable and the early reports may represent just the tip of the iceberg, no individual under age 30 under any set of circumstances should feel any obliged to take this risk with the current genetic vaccines.

38. The U.S. FDA has issued information on the J&J COVID-19 vaccine to include an update

[9] Abu Mouch S, Roguin A, Hellou E, Ishai A, Shoshan U, Mahamid L, Zoabi M, Aisman M, Goldschmid N, Berar Yanay N. Myocarditis following COVID-19 mRNA vaccination. Vaccine. 2021 Jun 29;39(29):3790-3793. doi: 10.1016/j.vaccine.2021.05.087. Epub 2021 May 28. PMID: 34092429; PMCID: PMC8162819.

[10] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021

about a serious type of blood clot for those who received this vaccine.[11] [12] In these cases, the type of blood clot is called cerebral venous sinus thrombosis and it was observed in combination with low levels of blood platelets. *Id.* All of these cases occurred in women between the ages of 18 - 48 and symptoms occurred 6 -13 days after vaccination. *Id.*

39. In general, it is not good clinical practice to widely utilize novel biological products in populations that have not been tested in registrational trials. For the COVID-19 vaccines this includes COVID-19 survivors, those with prior suspected COVID-19 infection, those with positive SARS-CoV-2 serologies, pregnant women, and women of childbearing potential who cannot assure contraception.

40. It is never good research practice to perform a large-scale clinical investigation without the necessary structure to ensure safety and protection of human subjects. These structures include a critical event committee, data safety monitoring board, and human ethics committee. These groups in large studies work to objectively assess the safety of the investigational product and research integrity with the goal of mitigating risk and protecting human subjects. It is my understanding that the COVID-19 vaccine program is sponsored by the CDC and FDA and has none of these safety structures in place. It is my assessment, that the COVID-19 clinical investigation has provided no meaningful risk mitigation for subjects (restricting groups, special assessment of side effects, follow-up visits, or changes in the protocol to ensure or improve safety of the program).

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[11] https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine

[12] https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine

COVID Vaccine Risks to College Age Students

41. The COVID-19 public vaccination program operated by the CDC and the FDA is a clinical investigation and under no circumstance can any person receive pressure, coercion, or threat of reprisal on their free choice of participation. Violation of this principle of autonomy by any entity constitutes reckless endangerment with a reasonable expectation of causing personal injury resulting in damages.

42. The current COVID-19 vaccines are not sufficiently protective against contracting COVID-19 to support its use beyond the current voluntary participation in the CDC sponsored program. A total of 10,262 SARS-CoV-2 vaccine breakthrough infections had been reported from 46 U.S. states and territories as of April 30, 2021. Among these cases, 6,446 (63%) occurred in females, and the median patient age was 58 years (interquartile range = 40–74 years). Based on preliminary data, 2,725 (27%) vaccine breakthrough infections were asymptomatic, 995 (10%) patients were known to be hospitalized, and 160 (2%) patients died. Among the 995 hospitalized patients, 289 (29%) were asymptomatic or hospitalized for a reason unrelated to COVID-19. The median age of patients who died was 82 years (interquartile range = 71–89 years); 28 (18%) decedents were asymptomatic or died from a cause unrelated to COVID-19. Sequence data were available from 555 (5%) reported cases, 356 (64%) of which were identified as SARS-CoV-2 variants of concern, including B.1.1.7 (199; 56%), B.1.429 (88; 25%), B.1.427 (28; 8%), P.1 (28; 8%), and B.1.351 (13; 4%). None of these variants are encoded in the RNA or DNA of the current COVID-19 vaccines. In response to these numerous reports, the CDC announced on May 1, 2021, that community breakthrough cases would no longer be reported to the public and only those vaccine failure cases requiring hospitalization will be reported, presumably on the CDC

website (https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm).

43. In 1990, the Vaccine Adverse Event Reporting Systems ("VAERS") was established as a national early warning system to detect possible safety problems in U.S. licensed vaccines.[1] VAERS is a passive reporting system, meaning it relies on individuals to voluntarily send in reports of their experiences to CDC and FDA. VAERS is useful in detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.

44. The total safety reports in VAERS all vaccines per year up to 2019 was 16,320. The total safety reports in VAERS for COVID Vaccines alone through Jun 18, 2021 is 387,288.

45. Based on VAERS as of June 18, 2021, there were 6,136 COVID-19 vaccine deaths reported and over 21,806 hospitalizations reported for the COVID-19 vaccines (Pfizer, Moderna, J&J). See VAERS COVID Vaccine Data, attached as Exhibit B. By comparison, from 1999, until December 31, 2019, VAERS received 3167 death reports (158 per year) adult death reports for all vaccines combined.[13] Thus, the COVID-19 mass vaccination is associated with at least 39-fold increase annualized vaccine deaths reported to VAERS.

46. COVID-19 vaccine adverse events account for 98% of all vaccine-related AEs from Dec 2020 through present in VAERS.

47. There are emerging trends showing that the vaccine is especially risky for those 18-29 in my expert medical opinion.

48. Increasingly the medical community is acknowledging the possible risks and side effects

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[13] Pedro L. Moro, Jorge Arana, Mria Cano, Paige Lewis, and Tom T. Shimabukuro, Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013, VACCINES, CID 2015:61 (September 2015).

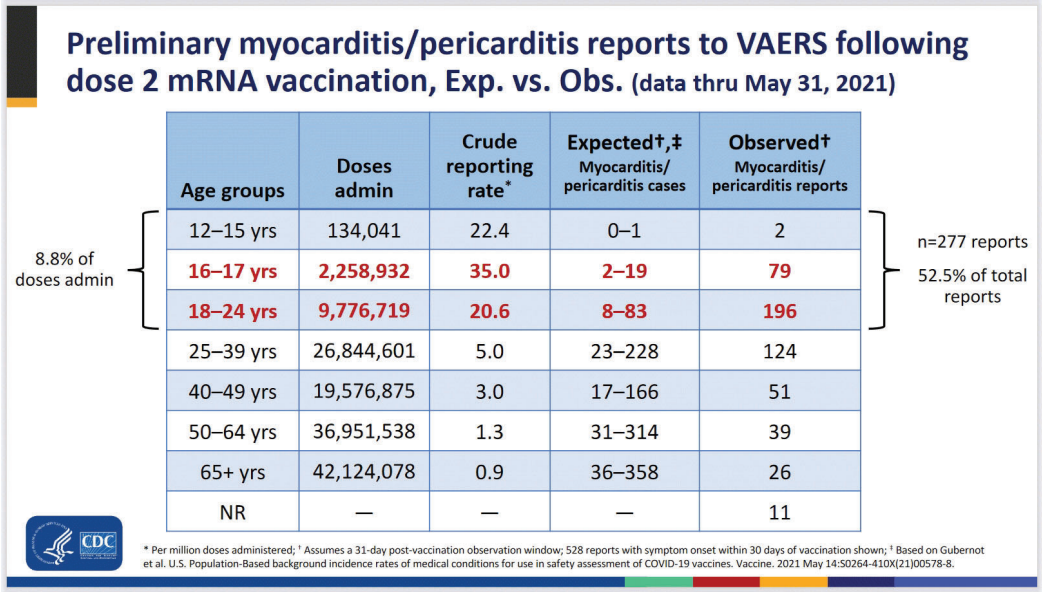
including myocarditis, Bell's Palsy, Pulmonary Embolus, Pulmonary Immunopathology, and severe allergic reaction causing anaphylactic shock. *See* Chien-Te Tseng, Elena Sbrana, Naoko Iwata-Yoshikawa, Patrick C Newman, Tania Garron, Robert L Atmar, Clarence J Peters, Robert B Couch, *Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus,* https://pubmed.ncbi.nlm.nih.gov/22536382/ (last visited June 21, 2021); Centers for Disease Control and Prevention, *Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020* (Jan 15, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm (last visited June 26, 2021).

49. Multiple recent studies and news reports detail people 18-29 dying from myocarditis after receiving the COVID vaccine. According to the CDC, 475 cases of pericarditis and myocarditis[14] have been identified in vaccinated citizens aged 30 and younger. *See* FDA, *Vaccines and Related Biological Products Advisory Committee June 10, 2021 Meeting Presentation*, https://www.fda.gov/media/150054/download#page=17 (last visited June 21, 2021).

50. The FDA found that people 12-24 account for 8.8% of the vaccines administrated, but 52% of the cases of myocarditis and pericarditis reported. *Id*.

[14] Myocarditis is inflammation of the heart muscle, whereas pericarditis is inflammation of the sac-like tissue around the heart called the pericardium.

Table 6: VAERS Report



Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. (data thru May 31, 2021)

Age groups	Doses admin	Crude reporting rate*	Expected†,‡ Myocarditis/ pericarditis cases	Observed† Myocarditis/ pericarditis reports
12–15 yrs	134,041	22.4	0–1	2
16–17 yrs	**2,258,932**	**35.0**	**2–19**	**79**
18–24 yrs	**9,776,719**	**20.6**	**8–83**	**196**
25–39 yrs	26,844,601	5.0	23–228	124
40–49 yrs	19,576,875	3.0	17–166	51
50–64 yrs	36,951,538	1.3	31–314	39
65+ yrs	42,124,078	0.9	36–358	26
NR	—	—	—	11

8.8% of doses admin

n=277 reports

52.5% of total reports

* Per million doses administered; † Assumes a 31-day post-vaccination observation window; 528 reports with symptom onset within 30 days of vaccination shown; ‡ Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8.

51. Further, the CDC just announced that the vaccine is "likely linked" to myocarditis. Advisory Board, *CDC panel reports 'likely association' of heart inflammation and mRNA COVID-19 vaccines in young people,* (June 24, 2021) https://www.advisory.com/daily-briefing/2021/06/24/heart-inflammation.

52. The CDC recently released data stating that there have been 267 cases of myocarditis or pericarditis reported after receiving one dose of the COVID vaccines and 827 reported cases after two doses through June 11. There are 132 additional cases where the number of doses received is unknown. *Id.*

53. There have been 1,200 reported cases of myocarditis that have occurred and the median age is thirty. *Id.*

54. The vaccine is also far less safe than previous vaccines like the meningicoccal meningitis vaccine that is typically required on college campuses.

55. For example, the VAERS (Vaccine Adverse Event Reporting System) data from the CDC shows, for 18-29 year olds, there have been no deaths from the meningicoccal vaccine from 1999 - 2019. See, United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC)/Food and Drug Administration (FDA), Vaccine Adverse Reporting System (VAERS) 1990 - 06/11/2021, CDC WONDER On-line Database. Accessed at https://wonder.cdc.gov/vaers.html on June 23, 2021 1:43:33 PM, ("Query Criteria"), Attached as Exhibit C.

56. The main side effects people reported from the meningitis vaccine are headache, injection site pain, nausea, chills, and a fever, and even these were limited as no more than fifteen of each were reported . *Id.*

57. However, in the brief time the COVID vaccines have been available, there have been many more serious symptoms and even a death reported for 18-29 year olds in Indiana. *See* Table 6, below. Nationwide VAERS COVID Vaccine Data through June 18, 2021 is attached as Exhibit B.[15]

Table 7: VAERS Data Indiana

Vaccine Adverse Event Reporting System (VAERS) Data for Indiana 18 to 29 Year Olds, Comparing Covid-19 and Influenza Vaccines

Vaccine-Associated Adverse Events Among 18 to 29 Year Olds in Indiana	Covid-19 Vaccines Given in <6 Months (Feb 1-June 4, 2021)[a]	Influenza Vaccines Given in >20 Years (2000-2021)[b]
Hospitalizations	23	13
Life Threatening Events	7	3
Myocarditis/Myopericarditis	7	0
Anaphylaxis/Severe Allergic Reaction	3	1*
Bell's Palsy (Facial Paralysis)	3	3
Pulmonary Embolus	1	0
Thrombocytopenia/Low Platelets	1	0
Deaths	1	0

[a,b] Using a very conservative comparison the denominator for the number of persons given influenza vaccines over 20 years would be at least 10-fold the denominator for the number of persons receiving covid-19 vaccines in the past < 6 months. Data accessed at the VAERS weblink, https://wonder.cdc.gov/vaers.html 6/12/21
* The individual received pneumococcal pneumonia vaccine in addition to influenza vaccine

[15] VAERS may be publicly accessed at https://www.openvaers.com/covid-data.

58. The World Health Organization said that children should not be vaccinated for the moment before they faced tremendous backlash. WHO, *COVID-19 Advice for the public: Getting vaccinated*, (Archived from April 8, 2021), https://web.archive.org/web/20210408183900/https:/www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/advice.

59. I have seen and examined college-age patients with post-COVID-19 myocarditis which typically occurs two days after the injection, most frequently after the second injection of mRNA products (Pfizer, Moderna). The clinical manifestations can be chest pain, signs and symptoms of heart failure, and arrhythmias. The diagnosis usually requires a clinical or hospital encounter, 12-lead electrocardiogram, blood tests including cardiac troponin (test for heart muscle damage), ECG monitoring, and cardiac imaging with echocardiography or cardiac magnetic resonance imaging. Given the risks for either manifest or future left ventricular dysfunction, patients are commonly prescribed heart failure medications (beta-blockers, renin-angiotensin system, inhibitors), and aspirin. More complicated patients require diuretics and anticoagulants. For post-COVID-19 vaccine myocarditis, I follow current position papers on the topic and restrict physical activity and continue medications for approximately three months before blood biomarkers and cardiac imaging are reassessed. If there is concurrent pericarditis, non-steroidal anti-inflammatory agents and colcicine may additionally be prescribed. Multiple medical studies are starting to come out detailing this problem.[16]

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[16] *See, e.g.,* Tommaso D'Angelo MD, Antonino Cattafi MD, Maria Ludovica Carerj MD, Christian Booz MD, Giorgio Ascenti MD, Giuseppe Cicero MD, Alfredo Blandino MD, Silvio Mazziotti MD, *Myocarditis after SARS-CoV-2 Vaccination: A Vaccine-induced Reaction?*, Pre-proof, Canadian Journal of Cardiology, https://www.onlinecjc.ca/article/S0828-282X(21)00286-5/fulltext (last visited June 26, 2021); Jeffrey Heller, *Israel sees probable link between Pfizer vaccine and myocarditis cases* (June 2,

60. Further, milder side effects from the vaccine include changes in hormone and menstrual cycles in women, fever, swelling at the injection site, etc. Jill Seladi-Schulman, Ph.D,, *Can COVID-19 or the COVID-19 Vaccine Affect Your Period?* (May 25, 2021), https://www.healthline.com/health/menstruation/can-covid-affect-your-period#covid-19-and-men%20strual-cycles (last visited June 26, 2021); Rachael K. Raw, Clive Kelly, Jon Rees, Caroline Wroe, David R. Chadwick, *Previous COVID-19 infection but not Long-COVID is associated with increased adverse events following BNT162b2/Pfizer vaccination*, (pre-print) https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1 (last visited June 26, 2021).

61. In an urgent report to the United Kingdom's Medicines and Healthcare Products Regulatory Agency ("MHRA") from Dr. Tess Lawrie, Director of the Evidence-Based Medicine Consultancy, and advisor to the WHO, on the UK's equivalent of the VAERS systems concluded that the vaccines were unsafe for use in humans due to the extensive side effects they are causing. Tess Lawrie, *Re. Urgent preliminary report of Yellow Card data up to 26th May 2021,* (June 9, 2021), http://www.skirsch.com/covid/TessLawrieYellowCardAnalysis.pdf

Risks of COVID Vaccines for Those Recovered from COVID

62. There is recent research on the fact that the COVID-19 vaccine is dangerous for those who

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2021), https://www.reuters.com/world/middle-east/israel-sees-probable-link-between-pfizer-vaccine-small-number-myocarditis-cases-2021-06-01/(last visited June 26, 2021); Tschöpe C, Cooper LT, Torre-Amione G, Van Linthout S. Management of Myocarditis-Related Cardiomyopathy in Adults. Circ Res. 2019 May 24;124(11):1568-1583. doi: 10.1161/CIRCRESAHA.118.313578. PMID: 31120823. Caforio AL, Pankuweit S, Arbustini E, Basso C, Gimeno-Blanes J, Felix SB, Fu M, Heliö T, Heymans S, Jahns R, Klingel K, Linhart A, Maisch B, McKenna W, Mogensen J, Pinto YM, Ristic A, Schultheiss HP, Seggewiss H, Tavazzi L, Thiene G, Yilmaz A, Charron P, Elliott PM; European Society of Cardiology Working Group on Myocardial and Pericardial Diseases. Current state of knowledge on aetiology, diagnosis, management, and therapy of myocarditis: a position statement of the European Society of Cardiology Working Group on Myocardial and Pericardial Diseases. Eur Heart J. 2013 Sep;34(33):2636-48, 2648a-2648d. doi: 10.1093/eurheartj/eht210. Epub 2013 Jul 3. PMID: 23824828.

have already had COVID-19 and have recovered with inferred robust, complete, and durable immunity. These patients were excluded from the FDA-approved clinical trials performed by Pfizer, Moderna, and J&J. From these trials the safety profile was unknown when the products for approved for Emergency Use Authorization in 2020.

63. A medical study of United Kingdom healthcare workers who had already had COVID and then received the vaccine found that they suffered higher rates of side effects than the average population. Rachel K. Raw, et al., *Previous COVID-19 infection but not Long-COVID is associated with increased adverse events following BNT162b2/Pfizer vaccination*, medRxiv (preprint), https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1 (last visited June 21, 2021).

64. The test group experienced more moderate to severe symptoms than the study group that did not previously have COVID. *Id*.

65. The symptoms included fever, fatigue, myalgia-arthralgia and lymphadenopathy. *Id*. Raw found that in 974 individuals who received the BNT162b2/Pfizer vaccine, those with a prior history of SARS-CoV-2 or those who had positive antibodies at baseline, had a higher rate of vaccine reactions than those who were COVID-19 naive. *Id.*

66. Mathioudakis et al. reported that in 2020 patients who underwent vaccination with either mRNA-based, or vector-based COVID-19 vaccines, COVID-recovered patients who were needlessly vaccinated had higher rates of vaccine reactions.[17]

67. Krammer et al. reported on 231 volunteers for COVID-19 vaccination, 83 of whom had positive SARS-CoV-2 antibodies at the time of immunization. The authors found: "Vaccine

[17] *See* https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1.

recipients with preexisting immunity experience systemic side effects with a significantly higher frequency than antibody naïve vaccines (e.g., fatigue, headache, chills, fever, muscle or join pains, in order of decreasing frequency, $P < 0.001$ for all listed symptoms, Fisher's exact test, two-sided)." (https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1).

Natural Immunity to COVID

68. To my knowledge, there are no studies demonstrating clinical benefit of COVID-19 vaccination in COVID-19 survivors or those who have laboratory evidence of prior infection.

69. It is my opinion that SARS-CoV-2 causes an infection in humans that results in robust, complete, and durable immunity, and is superior to vaccine immunity. There are no studies demonstrating clinical benefit of COVID-19 vaccination in COVID-19 survivors and there are three studies demonstrating harm in such individuals. Thus, it is my opinion that the COVID-19 vaccination is contraindicated in COVID-19 survivors many of whom may be in the college student population.

70. Multiple laboratory studies conducted by highly respected U.S. and European academic research groups have reported that convalescent mildly or severely infected COVID patients who are unvaccinated can have greater virus neutralizing immunity—especially more versatile, long-enduring T- cell immunity—relative to vaccinated individuals who were never infected. *See* Athina Kilpeläinen, et al., *Highly functional Cellular Immunity in SARS-CoV-2 Non-Seroconvertors is associated with immune protection*, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.05.04.438781v1 (last visited June 26, 2021); Tongcui Ma, et al., Protracted yet coordinated differentiation of long-lived SARS-CoV-2-specific CD8+ T cells during COVID-19 convalescence, bioRxiv (pre-print),

https://www.biorxiv.org/content/10.1101/2021.04.28.441880v1 (last visited June 26, 2021); Claudia Gonzalez, et al., *Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2*, medRxiv (pre-print), https://www.medrxiv.org/ content/10.1101/2021.05.11.21256578v1 (last visited June 21, 2021); Carmen Camara, et al. *Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals*, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.03.22.436441v1 (last visited June 26, 2021); Ellie N. Ivanova, et al., *Discrete immune response signature to SARS-CoV-2 mRNA vaccination versus infection*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255677v1 (last visited June 26, 2021); Catherine J. Reynolds, et al, *Prior SARS-CoV-2 infection rescues B and T cell responses to variants after first vaccine dose*, (pre-print), https://pubmed.ncbi.nlm.nih.gov/33931567/ (last visited June 21, 2021); Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1(last visited June 26, 2021).

71. Cleveland Clinic studied their own employees for the effects of natural immunity in unvaccinated people. Nabin K. Shrestha, Patrick C. Burke, Amy S. Nowacki, Paul Terpeluk, Steven M. Gordon, *Necessity of COVID-19 vaccination in previously infected individuals*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2 (last visited June 21, 2021). They found zero SARS-CoV-2 reinfections during 5-month follow-up among n=1359 COVID-19

recovered employees who remained unvaccinated and concluded such persons are *"unlikely to benefit from covid-19 vaccination." Id.*

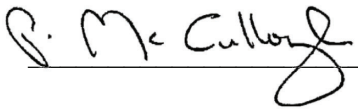
72. A recently published article in Nature reported that prior infection induces long-lived bone marrow plasma cells which means the antibodies to prevent reinfection of COVID are long-lasting. Jackson S. Turner et. al. *SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, (May 24, 2021), https://www.nature.com/articles/s41586-021-03647-4

Conclusion

73. In my expert medical opinion, the risks of COVID-19 to college age students in 2021 is significantly lower than in 2020 due to the following factors: rapidly declining COVID-19 infection rate, increasing likelihood of Indiana having reached herd immunity to COVID-19, low risk to college-aged students of serious complications or death due to COVID-19, low risk of asymptomatic spread of COVID-19, and vastly improved COVID treatments currently available. This is especially true because one-third of IU's populations is already likely to have immunity from prior infection. A university vaccine mandate or promotional policy that exerts any pressure, coercion, or threat of reprisal concerning the acceptance of any investigational biologic agent violates the medical ethics principle of autonomy. It is my clinical opinion that it is not good research or clinical practice to widely utilize novel biologic therapy (mRNA, adenoviral DNA COVID-19 vaccines) in populations where there is no safety information generated from the registrational trials with the FDA, specifically, on the following populations: COVID-19 survivors, suspected COVID-19 recovered, pregnant or women who could become pregnant at any time after investigational vaccines. Overall in the United States, 21,806 individuals have been hospitalized or worse after receiving one of the COVID-19 vaccines. In Indiana, among college

age adults, there have already been 23 hospitalizations or worse after they received COVID-19 vaccinations and far more can be expected if IU's Mandate is carried out. In my expert medical opinion, the risks associated with the investigational COVID-19 vaccines are not minor or unserious and can include hospitalization and death; the well-recognized risks (e.g., myocarditis, cerebral venous sinus thrombosis) more prevalent among college age students far outweighs any theoretical benefits. Many of those risks are unpredictable—at this time, the duration and extent of disability is impossible to calculate. Therefore, in my expert medical opinion, IU's Mandate that all non-exempted students take the COVID vaccine creates an unethical, unreasonable, clinically unjustified, not indicated, and unnecessary medical risk to its students.

I affirm under penalty of perjury that the foregoing is true and correct. Executed on June 28, 2021.



28-JUNE-2021

Dr. Peter A. McCullough